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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,432

06/13/2006

Nicolas Burdin

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02/18/2009

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EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,432	<b>Applicant(s)</b> BURDIN ET AL.	
	<b>Examiner</b> SHAWQUIA YOUNG	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-6 are currently pending in the instant application.

#### **I. *Response to Arguments/Remarks***

Applicants' amendment, filed on December 9, 2008, has overcome the rejection of claims 4-6 under 35 USC 112, first paragraph as failing to comply with the written description requirement for the term "imidazoquinolineamine derivatives"; the rejection of claims 1-6 under 35 USC 112, second paragraph as being indefinite for the terms "Toll-like receptor"; the rejection of claims 4-6 under 35 USC 112, second paragraph as being indefinite for the term "imidazoquinolineamine derivative"; the rejection of claims 5-6 under 35 USC 112, second paragraph as being indefinite for containing the phrase "preceding claim". The above rejections have been withdrawn.

Applicants traverse the claim objection of claims 1-6 as containing non-elected subject matter. However, Applicants' claims are drawn to vast subject matter that would be classified in various classes/subclasses and would require different search consideration. The Examiner wants to make clear that Applicants' claims are too broad to search in its entirety and thus the search will not be extended.

#### **II. *Rejection(s)***

##### **35 USC § 103 - OBVIOUSNESS REJECTION**

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Graham v. John Deere Co.* set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hawkins, et al.* (US Patent 6,290,973) and *Gerster, et al.* (US Patent 5,389,640) in view of *Janssens, et al.* Applicants' claims are drawn to an immunostimulant composition comprising at least one agonist of the Toll-like 7 receptor or of the Toll-like 8 receptor, wherein the composition additionally comprises an agonist of the Toll-like 4 receptor. Applicants have elected the an immunostimulant composition comprising the Toll-like 7 receptor agonist, 4-amino-2-ethoxymethyl- $\alpha,\alpha$ -dimethyl-1-H-imidazo[4,5c]quinoline-1-ethanol and the Toll-like 4 receptor agonist, ER804057.

**The Scope and Content of the Prior Art (MPEP §2141.01)**

*Hawkins, et al.* teaches immunological adjuvant compounds such as ER804057 (See column 6, line 45 and table 6, columns 187-188) that can be used in immunostimulatory compositions.

*Gerster, et al.* teaches 1H-imidazo[4,5-c]quinoline compounds such as 4-amino-2-ethoxymethyl- $\alpha,\alpha$ -dimethyl-1-H-imidazo[4,5c]quinoline-1-ethanol (See columns 35 and 36, examples 99 and 101) which can be used antivirals. The prior art reference further teaches compositions comprising the 1—imidazo[4,5c]quinoline compounds.

The secondary reference, *Janssens, et al.*, teaches the role of toll-like receptors in pathogen recognition. On page 639, the reference teaches that toll-like 7 receptors and toll-like 8 receptors have been shown to recognize synthetic antiviral compounds with strong immunostimulatory capacity belonging to the group of imidazoquinolines.

**The Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the prior art of *Hawkins, et al.* and *Gerster, et al.* and the instant invention is that Applicants have formulated an immunostimulant composition comprising of a toll-like 7 receptor agonist, 4-amino-2-ethoxymethyl- $\alpha,\alpha$ -dimethyl-1-H-imidazo[4,5c]quinoline-1-ethanol and a toll-like 4 receptor agonist, ER804057.

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**

Applicants are claiming an immunostimulant composition comprising at least one agonist of the Toll-like 7 receptor or of the Toll-like 8 receptor, wherein the composition additionally comprises an agonist of the Toll-like 4 receptor and have elected the an immunostimulant composition comprising the Toll-like 7 receptor agonist, 4-amino-2-ethoxymethyl- $\alpha,\alpha$ -dimethyl-1-H-imidazo[4,5c]quinoline-1-ethanol and the Toll-like 4

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receptor agonist, ER804057. The prior art reference of *Hawkins, et al.* teaches the compound ER804057 and its use in immunostimulatory compositions. The prior art reference *Gerster, et al.* teaches the compound 4-amino-2-ethoxymethyl- $\alpha,\alpha$ -dimethyl-1-H-imidazo[4,5c]quinoline-1-ethanol and its use in compositions as an antiviral. The secondary prior art reference *Janssens, et al.* teaches in general the role of toll-like receptors in pathogen recognition and specifically teaches that the imidazoquinoline class of compounds has strong immunostimulatory capacity which are ligands of Toll-like 7 receptors and Toll-like 8 receptors.

In In re Kerkoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980), it was well established that it is obvious to combine individual compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. Specifically, it is obvious to prepare an immunostimulant composition comprising a toll-like 7 agonist and a toll-like 4 agonist when the art teaches that a toll-like agonist can be used in immunostimulant composition and also teaches that a toll-like 7 agonist has strong immunostimulatory capacity with a reasonable expectation of success. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to prepare an immunostimulant composition comprising the Toll-like 7 receptor agonist, 4-amino-2-ethoxymethyl- $\alpha,\alpha$ -dimethyl-1-H-imidazo[4,5c]quinoline-1-ethanol and the Toll-like 4 receptor agonist, ER804057 based on the teachings of the preferred embodiments in the prior art. A strong prima facie obviousness has been established.

### **III. Objections**

#### **Claim Objection-Non Elected Subject Matter**

Claims 1-6 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

### **IV. Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Shawquia Young/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626